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December 16, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Assessing Consumer Perceptions of Health Claims; Public Meeting; Request for Comments [Docket No. 2005N-0413]

On behalf of the American Medical Association (AMA), I am pleased to offer comments to the Food and Drug Administration (FDA) on “qualified” health claims for conventional foods, as well as on recent research that assesses how disclaimers affect consumers’ ability to evaluate, understand and react to these health claims.

AMA opposes “qualified” health claims in the labeling of conventional foods

As previously communicated in letters dated February 21, 2003 and May 23, 2003 to FDA Dockets No. 02N-0515 and No. 03N-0069 respectively, the AMA vigorously opposes the use of “qualified” health claims in the labeling of conventional foods. The scientific evidence to support such claims is equivocal, ambiguous, and clearly inadequate to justify inclusion of “qualified” health claims on conventional food labels. Consumers are likely to be at best confused and at worst seriously misled by such claims.

Allowing “qualified” health claims in the labeling of conventional foods is contrary to federal law

In passing the Nutrition Labeling and Education Act (NLEA), Congress was explicit that health claims for conventional foods be based on the “significant scientific agreement” standard. In fact, Congress so acted because it was concerned about the increasing number of questionable and misleading health claims on conventional food products prior to passage of the NLEA.

In December 1999, the FDA published its *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, which clearly articulated that the “significant scientific agreement” standard was intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship. Furthermore, the FDA provided substantial detail on its expectations for the quality and consistency of the scientific evidence necessary to meet this standard and to gain approval for an [unqualified] health claim.

The AMA continues to believe the “significant scientific agreement” standard is appropriate for health claims on conventional foods; this standard provides reasonable assurance to a consumer that the health claim is accurate because the claim is supported by a significant body of scientific evidence.

No federal statute allows for “qualified” health claims, based on a lower evidentiary standard, in conventional food labeling. Thus, the FDA should not allow “qualified” health claims in the labeling of conventional foods.

Pearson v. Shalala does not apply to conventional foods

Unfortunately, in late 2002 the FDA made an administrative decision to allow “qualified” health claims, based on a lower evidentiary standard (the “weight of the scientific evidence” standard), in the labeling of conventional foods. The FDA has claimed that this was necessary to satisfy the opinion of the U.S. Court of Appeals for the District of Columbia Circuit in the case of *Pearson v. Shalala*. In this court case, dietary supplement marketers had sued the FDA for failing to authorize four health claims for dietary supplements. None of the health claims satisfied the “significant scientific agreement” standard that was being applied by the FDA, but the NLEA does not require this standard be used for dietary supplements. The Court held that FDA could not prevent the plaintiffs from using “potentially misleading” health claims on dietary supplement labels, provided proper disclaimers were used to correct for any possible deceptiveness in the claim. Such a health claim could be prohibited by FDA only if disclaimers fail to eliminate the potential deception.

The AMA strongly disagrees with the FDA that the Court decision in *Pearson* was intended to be applicable to conventional foods. In fact, the Court made an explicit distinction between conventional foods and dietary supplements in its written opinion, and the Court referred to – and did not question – the requirement in the NLEA that health claims on conventional foods must meet the “significant scientific agreement” standard. While the Court did criticize the FDA for not articulating what was meant by “significant scientific agreement,” the FDA’s subsequent publication of the aforementioned December 1999 *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements* should have satisfied the Court’s concerns in that regard.

To our knowledge, no Court has ever held that *Pearson* applies to health claims on conventional foods. Thus, the AMA believes the FDA should follow the statutory language in the NLEA and only allow health claims on conventional foods that satisfy the

“significant scientific agreement” standard. “Qualified” health claims, based on a lower standard of scientific evidence, should be prohibited.

Disclaimers are ineffective in communicating to consumers different levels of scientific support for health claims

Assuming, for argument’s sake, that the holding in *Pearson* does apply to health claims for conventional foods, the recent consumer research conducted by both the FDA and the International Food Information Council (IFIC) indicate that disclaimers are ineffective in helping consumers evaluate, understand and appropriately react to “qualified” health claims. For example, some key conclusions of the FDA staff report entitled, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims*, are as follows:

- Two disclaimer schemes that employed only text sentences, i.e., with different grammatical structure and adjectives to communicate the levels of scientific support for the claim, were entirely ineffective in conveying to consumers the strength of science supporting a health claim on food labels.
- When disclaimer schemes used report cards, i.e., A, B, C, or D, with associated text or graphics to reflect strength of science, consumers often erroneously believed that health claims with lower level disclaimers (e.g., B or C) were based on greater scientific certainty than [unqualified] health claims based on the “significant scientific agreement” standard.
- Consumer perceptions of product health benefit were unaffected by disclaimers, indicating that the disclaimers failed to effectively communicate the appropriate level of scientific support for a health claim.

Similar findings on the ineffectiveness of disclaimers have been reported by the IFIC Foundation, which is funded by the food industry.

These research data demonstrate that disclaimers fail to remedy possible deceptiveness of “qualified” health claims in the labeling of conventional foods. Thus, consumers are likely to be at best confused and at worst seriously misled by such claims. The AMA urges the FDA to prohibit the use of “qualified” health claims in the labeling of conventional foods.

Conclusion

There is no basis for the FDA to allow the use of “qualified” health claims in the labeling of conventional foods. Federal law (the NLEA) requires [unqualified] health claims for foods that are based on “significant scientific agreement,” the *Pearson* decision does not apply to conventional foods, and even if it did apply, recent scientific research has shown that disclaimers cannot remedy possible deceptiveness of “qualified” health claims.

The AMA urges the FDA to rescind its approval of all “qualified” health claims for conventional foods, and to prohibit the use of such claims in the future. Any health claim for a conventional food should be required to meet the “significant scientific agreement” evidentiary standard, as specified in the NLEA and as articulated by the FDA in its December 1999 Guidance.

The AMA appreciates the opportunity to comment on this important issue and would be pleased to respond to any questions from the FDA about our views.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is fluid and cursive, with the first name "Mike" and last name "Maves" clearly distinguishable.

Michael D. Maves, MD, MBA